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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,053	12/11/2006	Georgi Hvichia	P1024.0001/IUS	4866
54380	7590	07/13/2010	EXAMINER	
FLASTER/GREENBERG P.C.			BEISNER, WILLIAM H	
Four Penn Center				
1600 John F. Kennedy Boulevard			ART UNIT	
2nd Floor			PAPER NUMBER	
PHILADELPHIA, PA 19103			1797	
			NOTIFICATION DATE	DELIVERY MODE
			07/13/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/587,053	<b>Applicant(s)</b> HVICHIA, GEORGI	
	<b>Examiner</b> WILLIAM H. BEISNER	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-25 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-19 and 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/2/07 and 3/16/10</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 2-19 and 31-34, in the reply filed on 4/22/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 20-25 and 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/22/2010.

### ***Information Disclosure Statement***

3. The information disclosure statements filed 2/2/2007 and 3/16/2010 have been considered and made of record.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 2-19 and 31-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 of U.S. Patent No. 6,783,928 in view of Sato et al.(US 5,023,054) or Datar (US 6,008,040). Claims 1-52 of U.S. '928 encompass a device that includes a body and a lid with an obstacle device within a void formed by the body and lid. The instant claims differ by reciting that the obstacle is a stepped body. The references of Sato et al. and Datar both disclose that it is known in the art to separate particles flowing from inlet to an outlet using a stepped obstacle device (See Fig. 8 of Sato et al. and Fig. 4 of Datar). In view of these teachings, it would have been obvious to one of ordinary skill in the art to

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employ particle separating structures such as those disclosed by the references of Sato et al. or Datar for the known and expected result of providing an art recognized means for providing an obstacle to particles flowing in a stream of liquid.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 4-12, 14, 31, 32 and 34 rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al.(US 5,023,054).

With respect to claims 31 and 34, the reference of Sato et al. discloses a microscale device (Fig. 1 and 8) that includes a body (4, 5); a cover (3); and a separation element (2) wherein the body and cover define a void, inlet (6) and an outlet (7). The separation element (2) defines a first and second passageways wherein the height of the second passageway is smaller than the height of the first passageway (See Figure 8).

With respect to claim 32, the passageways are defined by steps and planar surfaces (See Fig. 8).

With respect to claim 2, the separation element is attached to the body (See Fig. 1).

With respect to claim 4, the inlet and outlet regions are defined by the body (See Fig. 1).

With respect to claim 5, the system includes a pump (See Fig. 5).

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With respect to claims 6 and 7, the device is capable of being filled with fluid and/or use with cells.

With respect to claims 8-12, the reference of Sato et al. discloses dimensions within the claimed ranges (See column 3, lines 47-65).

With respect to claim 14, the reference of Sato et al. includes an optical detector (See Fig. 5).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3, 8-13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al.(US 5,023,054).

The reference of Sato et al. has been discussed above.

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With respect to claim 3, while the reference is not clear as to whether the separation element (2) is integral with the body, in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to manufacture the components as an integral structure merely as an obvious means of design choice.

With respect to claim 8-12, if the dimensions of the device of Sato et al. do not meet the instant claim limitations, it would have been obvious to one of ordinary skill in the art to determine the optimal dimensions based merely on the specifics of the particles to be detected.

With respect to claim 13, in the absence of unexpected results, it would have been obvious to provide access channels in the system at various locations for the known and expected result of allowing separated particles to be removed from the restricted areas of the device for sampling.

With respect to claim 19, provisions of serially connected devices would have been well within the purview of one having ordinary skill in the art for the known and expected result of allowing different types of particles to be separated by using different separation elements designed for each particle type.

11. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al.(US 5,023,054) in view of Hale (US 5,089,384).

The reference of Sato et al. has been discussed above.

Claims 15-17 differ by reciting that the device further includes a device for killing cells.

The reference of Hale discloses that it is known in the art to selectively kill cells using a laser device (See Fig. 1).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a cell killing device as suggested by the reference of Hale for the known and expected result of selectively killing separated cells within the fluid stream trapped by the separation device.

12. Claims 18, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al.(US 5,023,054) in view of Datar (US 6,008,040).

The reference of Sato et al. has been discussed above.

Claim 18 differs by reciting the use of antibodies.

The reference of Datar discloses that the use of antibodies (8) within a stepped separation device (Fig. 4) is conventional in the art.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ antibodies within the steps of the primary reference for the known and expected result of facilitating the separation of the cells within the stepped regions as disclosed by the reference of Datar.

Claims 32 and 33 differ by specifying the structure of the steps.

The reference of Datar discloses that it is known in the art to employ a step configuration that includes a plurality of steps formed by planar surfaces at right angles (See Fig. 4).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ steps as disclosed in the reference of Datar in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the



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same result, separation and/or trapping particles in the flow of a fluid from an inlet region to an outlet region.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael A. Marcheschi, can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/  
Primary Examiner  
Art Unit 1797**

WHB

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